IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to: *Mitchell v. AbbVie Inc.*, No. 1:14-cv-09178	

PLAINTIFF'S RESPONSE TO ABBVIE'S MOTION TO EXCLUDE PEGGY PENCE

AbbVie moves to exclude Plaintiff's testing and labeling expert, Dr. Peggy Pence, contending that her expert opinions and testimony overlap with those of Dr. Kessler, Dr. Ardehali, Mr. Wojtanowski, and Mr. Miller and will be unfairly cumulative under Fed. R. Evid. 403. AbbVie's arguments fail.

As explained, Dr. Pence does not overlap with AbbVie's fact witnesses. And Drs. Pence, Kessler, and Ardehali reach separate and distinct opinions. Dr. Pence opines that AbbVie's testing and labeling were inadequate; Dr. Kessler opines that AbbVie's marketing and promotion improperly expanded the intended use beyond AndroGel's labeled indications; and Dr. Ardehali opines that AndroGel can cause heart attacks and did cause Mr. Mitchell's heart attack.

A. Dr. Pence is a Qualified Labeling Expert, While Mr. Wojtanowski and Mr. Miller Are Adverse Fact Witnesses.

Dr. Pence's expertise and opinions are focused to Plaintiff's theory that AbbVie negligently failed to warn about the risk of CV events posed by AndroGel, explaining the standard of care for a pharmaceutical company and how exactly AbbVie breached that standard vis-à-vis its AndroGel testing and labeling. Against the backdrop of more than forty years' experience and expertise in industry and based upon her review of record facts, Dr. Pence has arrived at ultimate expert *opinions* beyond the ken of a laymen. *See* Doc. No. 1897, at *35. She

prepared a Rule 26 report and was timely disclosed at the expert deadline, and she has cleared AbbVie's multi-pronged *Daubert* challenge. *See generally id.* The two opinions to which she has consistently testified are that: (1) as early to mid-2000s, AbbVie was aware of the need to conduct, and could have conducted, a study to adequately investigate the cardiovascular risk of AndroGel, *see* Trial Tr., *Mitchell I*, at 1896:1-14, attached hereto as Exhibit A; and (2) as early as 2007, AbbVie should have and could have strengthened the AndroGel labeling because there was reasonable evidence of a causal association between AndroGel and CV risk. *Id.* at 1894:9-21. Oregon law has long recognized the propriety of expert testimony to explain those concepts to a jury in a prescription drug failure-to-warn case. *See McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 535 n. 26 (Or. 1974) (rejecting defendants' claim that adequacy of prescription drug warning was not proper subject of expert testimony).

Comparing Dr. Pence to Mr. Wojtanowski and Mr. Miller, there is no material overlap or unfair cumulativeness because Dr. Pence is a Rule 26 expert. As the Court has correctly observed, "there's nothing that says you can't go through it with a company witness and then with an expert." *See* AbbVie Motion, Doc. No. 158, Ex. A, at 742:13-14. Mr. Wojtanowski and Mr. Miller are merely company fact witnesses being called as on cross by Plaintiff. They were not disclosed as experts or challenged under *Daubert*. While their testimony amounts to the begrudging admission of (or sometimes refusal to admit) a variety of damning facts, in no way do either of them articulate or offer the ultimate opinions that Dr. Pence will offer, *i.e.*, that AbbVie had a duty to, and *should have*, studied and warned.

Moreover, Plaintiff's real time examination of Dr. Pence has been short: 103 minutes in *Mitchell I* (81 on direct and 22 on re-direct) and 94 minutes in *Konrad II* (74 on direct and 10 on re-direct). Plaintiff's examination of Dr. Pence in the instant trial will be similar.

B. Drs. Pence, Kessler, and Ardehali Have Separate and Distinct Expert Opinions.

Notably, AbbVie does contend—nor could it—that Plaintiff is in violation of the "one expert, one topic" rule. For its part, AbbVie has, through their mixed fact / expert witnesses, highlighted the distinct roles that various people in the organization play in different functional capacities in the areas relevant to Plaintiff's claims: for instance, Mr. Wojtanowski on regulatory interactions and promotional review (with whom AbbVie has already conducted a fully structured direct on regulatory issues and elicited broad regulatory opinions); Mr. Miller on clinical trials and the adequacy of AbbVie's study of AndroGel; and Dr. Scarazzini on pharmacovigilance and signal assessment. *See also* AbbVie Demonstrative (used with Dr. Wotjanowski), attached hereto as Exhibit B. And so Plaintiff similarly, and properly, divides topics amongst his own experts: again, Dr. Pence on strengthened CV warnings and notice of the need, and duty, to test; Dr. Kessler on marketing and promotion; and Dr. Ardehali on causation.

Of course, Plaintiff's experts necessarily reviewed some of the same facts and documents, and to some extent they rely on and incorporate others' opinions. As the Court has recognized, it is entirely proper for one expert to rely on another expert's opinion as a basis for his or her own opinion. *See* Trial Tr., *Mitchell II*, at 6:20-23, attached hereto as Exhibit C. For example, Dr. Ardehali will opine that the scientific information available to AbbVie (including, *inter alia*, mechanism studies and biological data, clinical studies/analyses, and post-marketing adverse event reports) provided reasonable evidence of a causal relationship between AndroGel and CV events, and relying on that opinion, Dr. Pence will explain what duty arose as a result. *Compare* AbbVie Ex. A, at 1302:2-8 (Ardehali opining on reasonable evidence of causal association) *with* 2405:6—2407:8 (Pence specifically relying on Ardehali as cardiologist in forming opinion about notice to company).

This is the key difference between Plaintiffs' experts and AbbVie's general cause experts, which this Court addressed in its pretrial ruling. Although AbbVie's experts (French and Marais) have expertise in different fields, or as the Court commented "different walks of life," *see* Trial Tr., *Mitchell II*, at 5:16, at bottom they simply took divergent paths to arrive at the same endpoint, *i.e.*, the ultimate opinion that there is no causal connection between AndroGel and CV events. Unlike the overlapping and cumulative general causation testimony of French and Marais, Plaintiffs' experts have (1) different ultimate opinions, (2) relating to different theories of the legal claims and their elements. Plaintiff's approach here is more akin to separate experts handling general and specific causation, the propriety of which the Court has acknowledged. *Id.* at 5:9-10.

C. Dr. Pence's Testing Opinions Will Not Overlap with Other Expert Testimony.

Dr. Pence opines that AbbVie was on notice of the need to study—and should have studied—AndroGel to investigate the CV risk. AbbVie appears to cite two "overlaps" with Dr. Ardehali on this point, and both are *de minimus*. *See* AbbVie Motion, Doc. No. 158, at *2 (citing *Konrad II* Transcript, 1399:20-22), and *4 (citing *Konrad II* Transcript at 1429:18-23). More importantly, a closer look at both sections of testimony reveals that, in both instances, Dr. Ardehali was being asked foundational questions that helped to build to his opinion on general causation. *See* AbbVie Ex. A, at 1396:17—1398:16; and 1431:8—1432:6. The mention of the absence of studies to answer the CV risk question up to that point arose during the examination of Dr. Ardehali—in anticipation of AbbVie's use on cross-examination of excerpts of a 2010 FDA report, which elsewhere noted that well-powered, prospective studies to answer the CV safety question had not been done. It was not in any way cumulative and certainly not of the same nature as Dr. Pence's opinion, based on 40 years' experience in the pharmaceutical

industry, that a reasonable pharmaceutical company, on the basis of data then-available to AbbVie, would have initiated study.

The claimed overlap with Dr. Kessler is also illusory. AbbVie points to just sixteen lines of testimony, *see id*., at 748:7-22, without providing the context that Dr. Kessler was addressing the lack of a safety and efficacy study as foundation for his marketing opinions about "intended use." *See id.* at 748:23—751:2.[1]

D. Dr. Pence's Warning Opinions Will Not Overlap with Other Expert Testimony.

Here, the only expert overlap AbbVie cites is four lines of Dr. Ardehali's testimony—which was unsolicited by Plaintiff's counsel—as to how he would have acted, in his capacity as an industry consultant, upon review of adverse event reports. *See* AbbVie Motion, Doc. No. 158, at *2-3 (citing *Konrad II* Transcript, 1402:14-17). Dr. Ardehali will not testify to that again.

Dr. Ardehali will testify, as he is aptly qualified to do, that the scientific information available to AbbVie (e.g., mechanism studies and biological data, clinical studies/analyses, and post-marketing adverse event reports) as of a particular point in time provided reasonable evidence of a causal association between AndroGel and CV events. He will stop there. In turn, Dr. Pence will testify that, as a result, AbbVie had a duty to warn. But to be clear, if both Drs. Ardehali and Pence are called, Plaintiff does not intend to elicit duty or breach testimony from Dr. Ardehali and will instruct him accordingly.

[1] AbbVie also claims overlap with Wojtanowski and Miller on this point. Again, their testimony is factual in nature, confirming that AbbVie had not conducted a study, while Dr. Pence arrives at the expert conclusion that AbbVie should have done so.

E. Plaintiff's Experts' Discussion of FDA Background, AbbVie's Clinical Trials, Age-Related Hypogonadism, and FDA's 2015 Actions is Not Overlapping or Unfairly Cumulative.

As to FDA background, it is necessary that both Drs. Pence and Kessler discuss at least some regulatory background as a platform for their labeling and marketing opinions. But while the background might be similar, again, their ultimate opinions are not the same.

Any overlap with respect to discussion of AbbVie's clinical trials is only for the purpose of laying groundwork for separate and distinct opinions that serve different claims. For example, Dr. Pence examines AbbVie's 017 pre-approval study with an eye toward the safety information it revealed, which in turn informed her opinion that AbbVie should have been aware of the need to conduct a safety study early on in AndroGel's development. *See* AbbVie Ex. A, at 2390:6-7, 2391:22—2392:6. In contrast, Dr. Kessler discusses the study in order to explain his opinion about the scope of the approved, indicated use for AndroGel based on those study results. *See id.* at 740:8—741:3. Again, this is an instance of two experts examining the same or similar factual foundation in order to arrive at different, and independently relevant, expert opinions.

As to the handful of other areas highlighted in AbbVie's motion, close examination of each demonstrates the lack of overlap. For instance, as to the claimed overlap on age-related promotion, Dr. Pence's discussion of the topic is in service of her opinions relating to AbbVie's failure to test, *see* AbbVie Ex. A., at 2402:23—2403:23, while Dr. Kessler's discussion relates to his opinions that AbbVie's marketing of AndroGel was ultimately false and misleading. *Id.* at 764:23—766:11. Similarly, while both experts touch on FDA's 2015 actions, they discuss those actions separately, Dr. Pence addressing FDA's label changes in the context of negligent failure to warn, *see id.* at 2410:13-15, and Dr. Kessler opining on the addition of the age-related limitation of use, relating to whether AbbVie had prior notice of that limitation. *See id.* at 743:9-14.

CONCLUSION

Based on the foregoing, Dr. Pence's expert testimony does not "overlap" with that of AbbVie's company fact witnesses. And Plaintiffs experts, Drs. Pence, Kessler, and Ardehali, are distinct in their ultimate opinions. Dr. Pence should not be excluded.

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Respectfully submitted,

/s/Troy Rafferty

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CERTIFICATE OF SERVICE

I hereby certify that on March 10, 2018, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Troy Rafferty

Troy Rafferty